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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,980	09/08/2004	Alain Delache	062221	8796
38834	7590	02/16/2007	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			MATTER, KRISTEN CLARETTE	
		ART UNIT		PAPER NUMBER
				3771
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/16/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/506,980	DELACHE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Kristen C. Matter	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 January 2005.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-40 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 September 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/8/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first tube extremity, the second extremity, the mask, the filter, the memory, the comparator, the switch, and the frequency shift keying modulator must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: d1, d2, t1, t2, and t4.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 22, 35, 37, 38, 39, c1, K, R, 31, 102, 104, 106, 108, 112, 114, 116, 20, 122, 130, 132, t15, t16, t17, Dp, and Ek.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Specification*

The disclosure is objected to because of the following informalities:

On page 7, line 17, "well know" should be changed to --well known-- to correct the typographical error and on line 20, "the same value then" should be changed to --the same value as--;

On page 8, line 26, Applicant must delete reference to claim numbers;

On page 9, line 27 "of the E" should be changed to --of the--.

Furthermore, 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are the inclusion of variables without properly identifying what they represent. For example, on page 10, lines 25-35, Applicant does not state what PI, PE, and PWM represent and on page 10, it is unclear what AVP represents.

Appropriate correction is required.

*Claim Objections*

Claims 21, 23, 25, 30, 32, 35, 37, and 40 are objected to because of the following informalities:

Regarding claim 21, on line 3, "the first extremity" should be changed to --a first extremity; on lines 9-10, "the air output" should be changed to --an air output--; and on line 12, "on its said second extremity" should be changed to --on a second extremity--.

Regarding claim 23, on line 12, "on its said second extremity" should be changed to --on a second extremity--.

Regarding claim 25, on line 12 "the value" should be changed to --a value--.

Regarding claim 30, on line 3, "the means" should be changed to --a means--.

Regarding claim 35, on line 3, "estimator module" should be changed to --estimation module-- and on lines 3 and 5, "the mask pressure" should be changed to --the pressure--.

Regarding claim 37, on line 5, "the external power supply" should be changed to --an external power supply--.

Regarding claim 40, on line 19, "time" should be --times--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 21 and 23, it is unclear what pressure PM and pressure PB represent

Regarding claim 29, the pressures PM(J) and PB(J) lack antecedent basis and it is unclear what these values represent.

Claim 34 recites the limitation "said comparator" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 40, on line 19, it is unclear which steps “steps 5 to 6” are referring to.

Claim 22 is unclear for the reasons stated above with regards to claim 21.

Claims 23-28, 30-33, and 35-39 are unclear for the reasons stated above with regards to claim 23.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 29-34, 37, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,066,101) in view of Berthon-Jones (US 6,152,129).

Regarding claims 21-24 and 38-40, Johnson et al. discloses an airflow perturbation device and system comprising a shell(5) with a traversing hole (11) having a known resistance coefficient connected to a tube connected to a mouthpiece (see Figure 7), a first pressure sensor (4) for measuring mouth pressure, a second pressure sensor (2) for measuring airflow, and a control unit (computer). Johnson et al. is silent as to the airflow being generated by a blower or to an offset compensation means. Berthon-Jones discloses a device for determining leak and respiratory airflow comprising a blower (14) and a differential pressure sensor located on an opposite side of a pneumotachograph as a first pressure sensor. Berthon-Jones further discloses offset compensation means comprising leak flow calculations (see column 4, lines 40-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

have provided Johnson et al.'s device with a blower as taught by Berthon-Jones's for determining airflow resistance in patient's not able to comply with instructions (i.e., neonates, comatose patients). Furthermore, because Berthon-Jones's discloses a pneumotach already, it appears as though both devices would perform equally well in combination, and by providing Berthon-Jones's device with Johnson et al.'s device, airflow resistance could be calculated in addition to airflow alone in order to help evaluate respiratory disorders.

Regarding claim 30, Berthon-Jones discloses that the apparatus can be used in multi-level or autosetting treatment devices (i.e., Bi-PAP), which would inherently have a means for determining when a patient is inspiring or expiring (see column 8, lines 25-30).

Regarding claims 29, 31, and 32, Johnson et al. disclose a storage means for storing a plurality of sets of data over a period of time (see column 8, lines 15-20) and that adjustments to the resistance can be adjusted via an automatic feedback system based off of input to the computer regarding device and respiratory resistance data (see column 10, lines 10-20).

Regarding claims 33 and 34, Berthon-Jones device is capable of determining when a leak occurs, which is considered an event, or such as a change in inspiration/expiration in accordance with the multi-level treatment device.

Regarding claim 37, Berthon-Jones discloses that controller (42) receives information from microcontroller (38) and outputs a voltage to the motor (16) of the blower (see Figure 2a). Although Berthon-Jones does not explicitly disclose a FSK or a power source, his device is capable of transmitting voltage changes from binary data and the electric motor inherently has some sort of power supply.

Regarding claims 39 and 40, the modified device of Johnson et al. has all of the structural limitations recited in claims 39 and 40 and is fully capable of performing the recited process. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the claimed steps in order to calibrate the device.

Claim 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Hoffman (US 6,287,264).

Regarding claim 25, Berthon-Jones is silent as to how the offset compensation means and microcontroller (38) work. However, Hoffman discloses a system for measuring respiratory function comprising pressure differential measurements, a pneumotachograph, and a controller with analog to digital (A/D) converters (680) and an analog subtractor (670) for processing the pressure signals (see column 9, line 45-column 10, line 15). Johnson et al. also disclose A/D converters for processing the pressure signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the modified device of Johnson et al. with an analog subtractor as taught by Hoffman for subtracting out unwanted analog flow measurements during digital processing of the data and because these types of signal processing components are well known in the art.

Regarding claims 26 and 27, Johnson et al. discloses amplifiers and A/D converters connected between the computer and pressure sensors for use in processing said signals.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Orr et al. (US 2006/0117856). Johnson et al. is silent as to a filter. However, Orr et al. disclose a pressure transducer pneumotach with filters (29, 39) allowing resistance that is complimentary configured into the pressure transducers (i.e., a resistance coefficient would be known) connected to a ventilator and a computer (see paragraphs 32-36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the modified device of Johnson et al. with filters as taught by Orr et al. in order to prevent contamination of the pressure transducers from particulates.

Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. and Berthon-Jones as applied to claim 23 above and further in view of Estes et al. (US 5,551,418).

Regarding claim 35, Berthon-Jones does not disclose the specifics of changing blower speed with inspiration and exhalation. However, Estes et al. discloses a bi-PAP system that supplies higher pressure during inhalation and a lower pressure during exhalation (column 12, lines 40-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the modified Johnson et al. device with a bi-PAP system as taught by Estes et al. for increasing the comfort of the patient during breathing.

Regarding claim 36, Berthon-Jones does not disclose a starting means for determining when breathing activity is detected. Estes et al. disclose an automatic ON//OFF mechanism that detects the presence and absence of the patient (column 6, lines 5-35). It would have been

obvious to one of ordinary skill in the art at the time the invention was made to have provided the modified Johnson et al. device with an automatic ON/OFF mechanism as taught by Estes et al. in order to not waste power or air supply when it is unneeded.

*Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chowienczyk et al. (US 5,233,998) is cited to show a similar apparatus for measuring airway resistance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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2/13/07